K023309

NOV 1 2002

ATTACHMENT 5

510(k) Summary

510(k) Summary
Control Plasma N

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	October 2, 2002

2. Device Name/ Classification:

Control Plasma N / Multipurpose system for in vitro coagulation studies, Class II (864.5425)

3. Identification of the Legally Marketed Device:

Control Plasma N (K00125)

4. Device Description:

Control Plasma N is a lyophilized control prepared from pooled human plasma, stabilized with HEPES buffer solution. It is an assayed control intended to monitor and evaluate the precision and accuracy of coagulation and fibrinolysis tests in the normal range.

5. Device Intended Use:

Control Plasma N is assayed for use as an accuracy control for use of the following parameters in the normal range: Prothrombin time (PT); Activated partial thromboplastin time (aPTT); Thrombin time (TT)*; Batroxobin time*; Fibrinogen; Coagulation factors II, V, VII, VIII, vWfF IX, X, XI, XII and XIII**; Inhibitors: Antithrombin III, Protein C, Protein S, α_2 -antiplasmin, C_1 inhibitor**; Plasminogen; Total complement activity**, Lupus anticoagulants.
(* Not for BFT™II analyzer, ** Not available in the U.S.)

6. Medical device to which equivalence is claimed and comparison information:

Control Plasma N (modified) is substantially equivalent in intended use to the Control Plasma N (K001256) currently marketed. Control Plasma N (modified), like the current Control Plasma N is intended for use as an assayed quality control material to monitor the accuracy and precision of various coagulation and fibrinolysis tests in the normal range using a variety of mechanical and photo-optical coagulation systems.

7. Device Performance Characteristics:

Stability:

In duplicate determinations, reconstituted stability data met the acceptance criteria of recovering within the assigned values for the following claims: 4 hours at +15 to +25°C; 4 weeks at -20 to -30°C (2 hours after thawing at +15 to +25°C, stored for 4 weeks at -20 to -30°C).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2002

Ms. Donna A. Wolf
Senior Regulatory Affairs Specialist
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k023309
Trade/Device Name: Control Plasma N
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GIZ
Dated: October 2, 2002
Received: October 3, 2002

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: Control Plasma N

Indications for Use:

Control Plasma N is assayed for use as an accuracy control of the following parameters in the normal range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (aPTT)
3. Thrombin time (TT)*
4. Batroxobin time*
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, and XII
7. Inhibitors: Antithrombin III, Protein C, Protein S, α_2-antiplasmin,
8. Plasminogen
9. Lupus anticoagulants

* Not for BFT™II analyzer

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K023309

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use ____
(Optional Format 1-2-96)